REMARKS/ARGUMENTS

Claims 41, 44-51, and 54 are pending in the present Application.

I. Rejection under 35 U.S.C. § 112, First Paragraph

Claims 41 and 44-51 stand rejected under 35 U.S.C. § 112, first paragraph as allegedly failing to comply with the written description requirement, and as allegedly failing to comply with the enablement requirement. For the following reasons, this rejection is traversed.

A.) Written Description

It is well accepted that "There is a strong presumption that an adequate written description of the claimed invention is present in the specification as filed." *See* Synopsis of Application of Written Description Guidelines. Applicants submit that, viewing the specification and claims of the instant application, this requirement is more than adequately met.

First, attention is drawn to page 7, lines 17-30 of the instant application, wherein it is stated: "Currently, reboxetine is commercially available only as a racemic mixture of enantiomers, (R,R) and (S,S) in a 1:1 ratio, and reference herein to the generic name "reboxetine" refers to this enantiomeric, or racemic mixture. Reboxetine is commercially sold under the trade names of EDRONAX™, PROLIFT™, VESTRA™, and NOREBOX™. As previously noted, reboxetine has been shown to be useful in the treatment of human depression. Orally administered reboxetine is readily absorbed and requires once or twice a day administration. A preferred adult dose is in the range of about 8 to about 10 milligrams (mg). The effective daily dosage of reboxetine for a child is smaller, typically in a range of about 4 to about 5 mg. The optimum daily dosage for each patient, however, must be determined by a treating physician taking into account the patient's size, other medications which the patient may be taking, identity and severity of the particular disorder, and all of the other circumstances of the patient."

Also, at page 21, lies 23-24, it is stated: "The synthesis of racemic mixture of reboxetine is disclosed in Melloni *et al.* U.S. Patent No. 4,229,449.

In addition, applicants point out that the specification, at page 12, lines 14-21 states in relevant part that "Another embodiment of the present invention is directed to a method of treating or prevention a nervous system disorder comprising the step of administering a therapeutically effective dose of racemic reboxetine to an individual, wherein the disorder is at least one of...fibromyalgia..."

These excerpts from the specification clearly point out that reboxetine is commercially available, that the dosages are known, and that it is within the skill of an ordinary artisan to administer reboxetine. Furthermore, the specification expressly calls for a method to treat fibromyalgia. For these reasons, applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. § 112, first paragraph, written description.

B.) Enablement

The "test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation." (MPEP §2164.01, citing *In re Wands*, 858 F.2d 731, 737). Furthermore, the test for whether or not the enablement requirement has been met involves determining whether or not practice of the invention as claimed involves "undue experimentation". It has long been settled that "the key word is 'undue', not 'experimentation'". *In re Angstadt*, 190 USPQ 214, 219 (C.C.P.A. 1976).

"The information contained in the disclosure of an application must be sufficient to inform those skilled in the relevant art how to both make and use the claimed invention. However, to comply with 35 U.S.C. 112, first paragraph, it is not necessary to "enable one of ordinary skill in the art to make and use a perfected, commercially viable embodiment absent a claim limitation to that effect." *CFMT, Inc. v. Yieldup Int'l Corp.*, 349 F.3d 1333, 1338, 68 USPQ2d 1940, 1944 (Fed. Cir. 2003)." MPEP 2164

"When considering the factors relating to a determination of non-enablement, if all the other factors point toward enablement, then the absence of working examples will not by itself render the invention non-enabled. In other words, lack of working examples or lack of evidence that the claimed invention works as described should never be the sole reason for rejecting the claimed invention on the grounds of lack of enablement." MPEP 2164.02

In the present case, the application of the current technology requires routine effort and not undue experimentation. Referring to the same portions of the specification noted above, for support of written description, it is respectfully submitted that the enablement

requirement is met. There is, in fact, a commercial embodiment of reboxetine presented. Also, the routes of administration, dosing regimens and dosages are not only stated in the specification, but are present as dependent claims 44-50. Any experimentation (which is not admitted to be present), would be routine and within the ordinary skill in the art. For these reasons, applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. § 112, first paragraph, enablement.

V. Conclusion

If the Examiner believes a telephonic interview with Applicant's representative would aid in the prosecution of this application, the Examiner is cordially invited to contact Applicant's representative at the below listed number.

Respectfully submitted,

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